

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY, INC.)
PRODUCTS LIABILITY LITIGATION)
) **MDL No. 1:13-md-2419**
) **Judge Rya Zobel**
This Document Relates to:)
) **All Actions Involving Specialty Surgery**)
Center and Dr. Kenneth Lister.)

**PLAINTIFFS' STEERING COMMITTEE'S REPLY IN SUPPORT OF MOTION TO
COMPEL SPECIALTY SURGERY CENTER AND DR. KENNETH LISTER**

The Plaintiffs’ Steering Committee (“PSC”) files this Reply in Support of its Motion to Compel SSC and Dr. Kenneth Lister. Although the defendants have addressed or clarified a handful of issues,¹ they introduces new facts that (once again) raise more questions than answers, and they fail to address (1) that there is evidence of the spoliation of records other than the drug formulary itself, (2) that spoliation can occur even without intentional conduct by individuals, and (3) even if SSC did not destroy the 2010-2012 drug formulary itself (or destroy any records, for that matter), Tennessee law requires only the **concealment or falsification** of evidence to justify lifting the default non-economic damages cap, and the evidence sought is intrinsically relevant to the plaintiffs’ claims in the first place. In light of these issues, the Court should order the depositions of Atkinson and Dr. Lister to proceed without limitation, order production of the litigation hold letter, order the immediate production of certain ESI, and order disclosures and a meet and confer concerning additional electronic records as requested herein.

¹ The defendants have clarified that they conducted an undated search for hard copy documents. The defendants also have provided information sufficient to evaluate their claims of privilege (sender, recipients, and subject matter) for their redactions to certain records produced in response to the PSC 2nd RFPs —disclosures which the defendants should have made in the first place. However, as explained herein, the PSC disputes that SSC has searched “all relevant custodians” for records.

I. Relevance of the Information to Sanctions, the Damages Cap, and Other Matters

A. SSC Spoliated Evidence, and a Showing of Individual Intent is Not Required

As the PSC has explained, on September 28, 2015, Gina Calisher testified that she added Depo-Medrol to SSC's formulary in April 2013 at Jean Atkinson's direction, that SSC maintained the 2012 version of the formulary in both hard copy and electronic form prior to the April 2013 revisions, and that she emailed revisions to Atkinson (with revisions in bold) in response to a handwritten or facsimile communication from Atkinson (as reflected in the document bearing Bates stamp CAL-00300). As the PSC pointed out in its October 1, 2015 email to SSC's counsel, SSC's production did not contain (among other things) any communications to Gina Calisher to make the modifications, any documents instructing Atkinson to make these modification to the formulary,² or any documents showing modifications made by Atkinson to CAL-00300, which included bolded text, spelling mistakes, and other text that was not contained in the revised version of the formulary ultimately produced to the SSC as Exhibit 91. In addition to documentation instructing Atkinson to make the changes to the formulary, no minute or order from the Medical Executive Committee has been produced that adopted and approved the April 2013 revisions to the drug formulary, which raises the question as to whether the document was every adopted and should have been included in the policies and procedures manual or whether it was created solely for litigation purposes.

SSC still has not produced any of these three categories of records, including at least one handwritten or fax communication from Atkinson to Calisher (directing Calisher to make changes to the formulary) that unquestionably existed. Assuming that SSC conducted a thorough search for records and could not locate a copy of these documents, it is apparent that relevant

² Atkinson was an employee of SSC and presumably acted at the behest of someone else at SSC (perhaps Dr. Lister or the Executive Committee) with respect to changing the formulary.

documents were destroyed, which constitutes the spoliation of evidence. Furthermore, given the revelation (six months after her deposition) that Atkinson disregarded her document preservation obligations despite the presence of a litigation hold, there is a reasonable prospect that additional records were destroyed or lost – an open question that the PSC cannot answer without appropriate discovery.

Spoliation of evidence permits the trier of fact to infer from the party's obliteration of a document relevant to a litigated issue that the contents of the document were unfavorable to the party.³ To lay the necessary foundation for a spoliation negative inference, the sponsor of the inference must proffer evidence sufficient to permit the trier of fact to find that the party against which the inference is sought to be made knew of (1) the litigation or the potential of litigation, and (2) the potential relevance of the missing evidence to the litigation.⁴ "[W]hether the particular person who spoils evidence has notice of the relationship between the evidence and the underlying claim is relevant to the factfinder's inquiry, but it does not necessarily dictate the resolution of that inquiry."⁵ "The critical part of the foundation that must be laid depends, rather, **on institutional notice – the aggregate knowledge possessed by a party and its agents, servants, and employees.**"⁶ Thus, even where no particular employee of a company appreciated the relevance of particular records to prospective or pending litigation when the records were destroyed, the jury may draw a negative inference concerning spoliation of that evidence where the employer had notice of the relevance of those records to the lawsuit.⁷ In other words,

³ *Testa v. Wal-Mart Stores, Inc.*, 144 F.3d 173, 177 (1st Cir. 1998).

⁴ *Testa*, 144 F.3d at 177.

⁵ *Testa*, 144 F.3d at 177-78.

⁶ *Testa*, 144 F.3d at 178 (emphasis added).

⁷ *See Testa*, 144 F.3d at 178 (finding that destruction of records was sufficient to support a negative inference, where there was no proof that the employee that destroyed the records was aware of the litigation or the relevance of those records to it); *see also Blinzler v. Marriot Int'l*,

“[w]hen the evidence indicates that a party is aware of circumstances that are likely to give rise to future litigation and yet destroys potentially relevant records without particularized inquiry, a factfinder may reasonably infer that the party probably did so because the records would harm its case.”⁸

Here, the defendants admit that they were aware of potential litigation by October 2012, SSC does not dispute that records concerning its drug formulary are relevant, and at least some those documents have been destroyed or are missing. Accordingly, an appropriate foundation has been laid at least with respect to Atkinson’s initial communication to Gina Calisher, as well as with respect to the lack of any records of communications to Atkinson about changing the formulary or Atkinson’s edits to the revised version of the formulary that she received from Calisher. Whether the jury believes SSC’s explanation for the destruction of records, whatever that explanation may be, would be a credibility question for the trier of fact.⁹

Finally, the existing record demonstrates that Atkinson (if not others at SSC) disregarded her litigation hold obligation in advance of the sale of SSC’s assets to Cumberland. This raises the legitimate prospect that SSC did not preserve other relevant records during this time frame, justifying further discovery by the PSC to determine the scope of the issue and to gather additional evidence to support a negative inference at trial.

B. The Tennessee Economic Damages Cap

81 F.3d 1148, 1159 (1st Cir. 1996) (“The proponent of a ‘missing document’ inference need not offer direct evidence of a coverup to set the stage for the adverse inference. Circumstantial evidence will suffice.”)

⁸ *Blinzler*, 81 F.3d at 1159.

⁹ *See, e.g., Pelletier v. Magnusson*, 195 F. Supp. 2d 214, 236 (D. Me. 2002) (“[T]he defendants’ explanation, if they have one, for why the documents are missing is an issue credibility that can be left for trial”).

The defendants do not acknowledge – let alone rebut – the PSC’s contention that evidence concerning efforts by SSC to destroy, falsify, or conceal records is relevant to whether Tennessee’s economic damages cap applies here. As the PSC explained in its opening brief, Tennessee law imposes a \$750,000 cap on non-economic damages, but lifts that cap where “[t]he defendant intentionally **falsified**, destroyed, or **concealed** records containing material evidence with the purpose of wrongfully evading liability in the case at issue.”¹⁰ As the statutory language makes clear, the destruction of material evidence is **not required** for the damages cap to be lifted – the act of falsifying or concealing records is sufficient.¹¹

Here, in addition to the destruction of at least one relevant record (the initial communication from Atkinson to Calisher concerning changes to the formulary), the existing record demonstrates that SSC altered material evidence despite the presence of a litigation hold obligation, and that it may have concealed evidence in responding to document requests. In addition, the April 2013 drug formulary that was submitted to the PSC as the drug formulary that was in effect as of 2012, has never been approved or made effective by the Medical Executive Committee¹². Under Tennessee law, the PSC is therefore entitled to reach the jury on whether the exception to the statutory damages cap applies, and discovery related to the elements of that exception is justified to prevent prejudice to the PSC at trial on that issue.

¹⁰ Tenn. Code Ann. 29-39-102(h)(2) (emphases added)

¹¹ This damages cap and the associated exception to it became effective on October 1, 2011. *See* 2011 Tenn. HB 2008. The PSC has not located any Tennessee caselaw interpreting or applying this exception.

¹² This is subject to additional discovery. Currently, the position of SSC is that no Medical Executive Committee minutes exist that mention the drug formulary, i.e. the 2013 new formulary was never actually adopted.

C. General Relevance of the Information Sought

Even without regard to sanctions or the damages cap, SSC's shoddy medication practices and procedures are squarely at issue in this lawsuit. Consistent with the plaintiffs' theory of the case, the record shows that SSC played fast and loose with its drug formulary. By its own terms, the formulary purported to list all of the medications approved for use as safe and effective, based on review and approval by SSC's Executive Committee. SSC now contends that it utilized Depo-Medrol for over a decade without placing the drug on its formulary, and that it (supposedly) altered the formulary in April 2013 without approval by the Executive Committee. This raises legitimate questions about whether SSC was always this cavalier with regard to its policies and procedures: were earlier revisions to the formulary authorized by the Executive Committee or implemented unilaterally by Atkinson or others? Did SSC even track what drugs were on the formulary relative to the drugs used at the clinic? Should the jury take any of SSC's written policies and procedures at face value? These are legitimate lines of inquiry with serious implications for the jury's evaluation of the evidence at trial. Although SSC and Dr. Lister contend that additional discovery should be limited, the PSC cannot know at this point where these lines of inquiry (and others discussed herein) might lead.

II. Counsel's Involvement in Production of the Drug Formulary

SSC's counsel represents that it collected evidence from SSC on October 11 and 12, 2012, again in April 2013 "when it became clear that the sale of SSC's assets would be completed in June 2013," and again at an unspecified point before making its original document production in October 2014. Counsel for SSC admits that during one of these trips (counsel does not specify), it collected both the older versions of the policy and procedure manual and the April 2013 version.

When the PSC first raised concerns about SSC's prior productions following the Calisher deposition, counsel for SSC gave the impression that it had copied only the 2013 version of the manual in response to the PSC's 1st Set of RFPs.¹³ In its response to the Interrogatory associated with the 2nd RFAs, SSC reiterated this position, stating that it "made a copy of its full policy and procedure manual after receiving the Plaintiffs' First Request for Production in October 2013."¹⁴ The interrogatory response also blamed an unnamed "former SSC employee from SSC's billing department", who allegedly assisted in collecting records, for copying the wrong document.¹⁵

However, in its response to the Motion to Compel, counsel effectively admits that this was only half the story: counsel for SSC now discloses that it collected **both** the earlier versions of the policy (including the version in place in 2012) and the revised (April 2013) version when responding to the PSC's document requests. Despite apparent discrepancies on the face of the April 2013 version, counsel elected to produce only the later version, apparently without conducting any due diligence (such as asking the client) about which version to produce. Additionally, since the April 2013 version does not have an effective date, Counsel never went to the Medical Executive Committee minutes or members to determine when, if ever, that version was adopted and became effective. This new position is difficult to square with its previous representations to the PSC about why the revised version of the formulary was produced instead of the correct version.

¹³ See Dkt. No. 2496, Ex. 19 at p. 4 (indicating that counsel produced the "Approved Medication List" that "was included the P/P manual I picked up that day", and that "we had no reason to believe it was not the one in place in 2012").

¹⁴ Dkt No. 2496, Ex. 9, at p. 2.

¹⁵ *Id.*

III. The Litigation Hold Letter is Discoverable

As the PSC has explained herein, Gina Calisher’s testimony and the email exchanges between her and Atkinson demonstrate that multiple documents have been destroyed. The defendants **do not dispute** that discovery of the litigation hold letter is appropriate where there is evidence of spoliation. Having made (at a minimum) a preliminary showing of spoliation, production of the litigation hold letter is therefore justified.¹⁶ Indeed, legitimate questions remain as to the substance, dissemination, and efficacy of the litigation hold letter.¹⁷

IV. Dr. Lister’s and Atkinson’s Testimony Concerning the Formulary

Remarkably, the only explanation for the testimony of Dr. Lister and Ms. Atkinson related to the formulary comes in a footnote, in which counsel states that Dr. Lister and Ms. Atkinson “did not know” or “did not remember” that the formulary had been updated in April 2013. Implicitly, the defendants concede that Lister and Atkinson did not give accurate testimony at their depositions. The PSC is entitled to hear from the witnesses themselves, not from counsel, why they did not testify accurately (or perhaps truthfully). Moreover, Dr. Lister’s testimony is particularly suspicious: the fact that he maintained that “Depo Medrol was on the

¹⁶ See *Major Tours, Inc. v. Colorel*, 2009 U.S. Dist. LEXIS 68128 (D.N.J. Aug. 4, 2009) (collecting cases and granting motion to compel production of litigation hold notice, where plaintiff made a “preliminary showing of spoliation of evidence”); *Magnetar Techs. Corp. v. Six Flags Theme Park, Inc.*, 886 F. Supp. 2d 466, 482 (D. Del. 2012) (“[T]here has been a growing trend among courts to find the attorney-client privilege is lost when spoliation has occurred Although, in general, litigation hold letters are privileged, courts have adopted the view that the when spoliation occurs those letters become discoverable.”)

¹⁷ SSC’s attorneys claim to have communicated a litigation hold on October 12, 2012 via email to unidentified “point of contacts” at SSC. Dkt No. 2565, at p. 4. Because SSC has declined to identify those “points of contact”, it remains unclear whether Atkinson or Lister even received it (or read it), or to whom it was disseminated.

formulary” indicates that he knew that it was added at some point and that he was answering carefully.¹⁸

V. Scope of the ESI Search

The defendants’ opposition confirms what the PSC originally believed: that counsel for SSC did not actually review the original production, but instead ran search terms without disclosing the nature of that search or searches to the PSC.¹⁹ SSC claims that its searches were gratuitous because the ESI Protocol (Dkt No. 1087) did not require SSC to run additional search terms. That is a disingenuous position: the ESI Protocol established that parties were under no obligation to go back to the custodian’s **original files** to run search terms – not that counsel for a party was relieved of any obligation to review or search for terms within the results generated by that search for responsiveness to future document requests.²⁰

At any rate, the defendants offer no explanation as to why Atkinson, Bowlin, and Austin are the only document custodians with potentially relevant records. The Executive Committee at SSC was required to approve any changes to the formulary, indicating that either (a) the Executive Committee approved these changes without regard to the litigation hold obligation; or

¹⁸ When the PSC indicated that Dr. Lister seemingly “was prepared” to answer these questions carefully, the PSC did not state that counsel for SSC had engaged in misconduct by preparing Dr. Lister to give false testimony. It may be that Dr. Lister, of his own volition, prepared himself to give artfully evasive answers to questions concerning the formulary.

¹⁹ In meet and confer discussions, the PSC recalls that SSC maintained that it would not search for or produce 2013 records. In spite of that earlier representation, SSC has apparently conducted an undated search for electronic records. The remaining point of conflict is that SSC apparently did not include all ESI from 2013 and refused to go back to the client to gather additional ESI that would encompass all of the 2013 records. This might explain why the missing documents have not been produced.

²⁰ SSC seems to be taking the position that, in response to document requests from the PSC, it is under no obligation either to (a) review the previously generated dataset for responsive documents, or (b) to run search terms or conduct other searches of the dataset. That cannot be the case – otherwise, SSC would essentially have no obligation to review or search its ESI dataset at all in responding to the PSC’s document requests.

(b) SSC made changes to the formulary in violation of, and without regard for, its own policies and procedures. Neither answer reflects favorably on SSC, and the PSC is entitled to know what happened in support of its arguments relating to spoliation, the exception to Tennessee's economic damages cap, and the general relevance of SSC's handling of medication policies and procedures that impact patient safety. As to relevant custodians of this information, SSC takes the position that the email accounts of its Executive Committee members are outside of SSC's possession, custody, or control because they are personal email accounts. If that is in fact the case, the Court should simply order SSC to identify and provide contact information for the Executive Committee Members, and authorize the PSC to issue subpoenas to those custodians to obtain relevant electronic records.

As to the burden of searching for relevant records, it remains unclear to the PSC exactly what limitations SSC unilaterally placed on its ESI search. The only reference to search terms is contained in a footnote that states that, "[f]or instance, searches were run for: Formulary, Approved Medications, Medication List, *etc.*" It is not clear from that footnote what other search terms were utilized, nor is it clear whose documents were searched.²¹ It is also unclear exactly what was searched as SSC has previously refused to go back and add 2013 ESI to the larger dataset for searches and review. The PSC should not be left to guess at what limitations counsel for SSC is placing on its responses, and the PSC certainly cannot be faulted for not "attempting to present any reasonable compromise" where SSC is imposing unilateral undisclosed limitations on its document searches.

²¹ At one point, SSC's brief indicates that it searched the email accounts of Bowlin, Atkinson, and Austin, but another part of the brief suggests that it searched all of the ESI returned by the PSC's original terms. *See* Dkt No. 2565 at pp. 10-11.

At a minimum, the Court should order SSC (1) to identify all limitations that it has placed on its search for responsive ESI in response to each document request (whose records were searched, whether counsel or the client conducted a search, what search terms were utilized, what date limitations were imposed, the exact data set that is being searched, *etc.*), (2) to produce or to facilitate the production of responsive electronic records from the other Executive Committee members (by subpoena or otherwise), (3) to review and produce, immediately, all of its responsive electronic records for the time frame from January 1, 2013 through the SSC's sale to Cumberland later that year, and (4) to meet and confer with the PSC to identify reasonable limitations on the nature and scope of ESI searches relative to each document request.

VI. Depositions of Atkinson and Lister Without Limitation

On October 12, 2015, in an effort to move discovery along without court intervention, the PSC initially offered to depose SSC and Dr. Lister on specified topics.²² The PSC made the representation before it received discovery responses from SSC that raised additional issues concerning potential spoliation, SSC's document production efforts, and SSC's evolving explanations for its failure to produce the drug formulary. SSC's opposition brief, which raises even more issues (as detailed herein) reinforces the PSC's position that a deposition without limitations is justified because it is unclear where the PSC's lines of inquiry might lead.²³

²² See Dkt No. 2565, Ex. 6, at p 2.

²³ If the Court is not inclined to permit the depositions of Atkinson and Dr. Lister to go forward without limitation, it should adopt the limitations set forth in Mr. Stranch's October 12, 2015 email and permit questioning regarding the formulary, document retention policies, modifications to the formulary, SSC's post-outbreak investigation, and the verification of its interrogatory responses and the nature of its production as they relate to the formulary and to the PSC's 2nd RFPs.

Date: January 12, 2016

Respectfully submitted:

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 11, 2015

/s/ Benjamin A. Gastel
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